IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

John Eichin, Plaintiff, vs. Ethicon Endo-Surgery, Inc., and Ethicon Endo-Surgery, LLC., Defendants.	)	Case No.4:21-cv-03274-JD **Order and Opinion**

This is a products liability case that arises out of injuries sustained by Plaintiff John Eichin ("Eichin" or "Plaintiff") during a surgical operation. Before the Court are two motions. Defendants Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (collectively "EES" or "Defendants") move for Summary Judgment under Rule 56, Fed. R. Civ. P. (DE 75), on all claims brought against them in the Second Amended Complaint (DE 41).[1] On the other hand (and to defend against EES's motion for summary judgment), Eichin moves to amend the Fifth Amended Scheduling Order in

[1] Plaintiff filed this suit on October 6, 2021, against now-former defendants Covidien LP, Covidien Sales LLC, Covidien Holding, Inc., and Medtronic, Inc. ("Covidien Defendants"). (DE 1.) On October 10, 2022, Plaintiff filed a Second Amended Complaint (DE 41) asserting three claims: (1) "Strict Products Liability Manufacturing Defect," (2) "Negligence," and (3) "Strict Products Liability – Failure to Warn." (*Id.* at 13–17 ¶¶ 43–63.) Plaintiff also added two new defendants: Johnson & Johnson and Ethicon, Inc. Both Johnson & Johnson and Ethicon, Inc. were removed from the pleadings and replaced with EES. (DE 62.) Eichin further dismissed the Covidien Defendants by "Stipulation of Dismissal Without Prejudice . . . ." (DE 70.)

this case (DE 69) to extend the expert disclosure deadline so that he can retain an expert since the deadline to do so has passed.[2] (DE 77.)

After reviewing the motions, memoranda submitted, and the record, the Court denies Plaintiff's "Motion to Amend the Scheduling Order" (DE 77) and grants Defendants' Motion for Summary Judgment (DE 75).

BACKGROUND

A. Plaintiff's Condition

In July 2019, Plaintiff was hospitalized for abdominal pain and diagnosed with diverticulitis. (DE 75-2 at 7-8, Pl's. Dep. 79:12–80:17.) In September 2019, Plaintiff again was hospitalized for abdominal pain and diagnosed with his second bout of diverticulitis. (DE 75-3 at 10–11, Baughman Dep. 58:17–59:12.) This time, the diverticulitis caused a perforation in his colon. (*Id.* at 11, 59:9–25.) A colonoscopy revealed that Plaintiff had diverticulitis throughout his colon, but most acutely in his sigmoid colon. (*Id.* at 14, 86:3–13.) It also revealed that Plaintiff had a sessile polyp in his sigmoid colon that was concerning for its potential to be cancerous. (*Id.* at 12–13, 84:13–85:22.)

B. Plaintiff's Proposed Treatment

Plaintiff elected to undergo surgery (specifically, a sigmoidectomy) to remove a portion of his sigmoid colon (DE 75-2 at 11, Pl's. Dep. 100:10–14), i.e., the area between his "descending" colon and his rectum. (DE 75-3 at 15–16, Baughman Dep.

[2] The original expert deadline was June 8, 2022. (DE 23.) This Court then extended that deadline four times: first to September 23, 2022, (DE 31); then to December 22, 2022, (DE 37); then to December 15, 2023, (DE 56); and finally, to March 15, 2024. (DE 69.)

87:10–88:7; *Id.* at 19, 121:3–11.) Following the removal of the sigmoid colon, Plaintiff's "descending" colon would be connected to the portion of his colon near his rectum through an "anastomosis," where the two ends of the colon are reconnected. (*See generally id.* at 21–22, 124:16–125:19; *id.* at 23, 128:3–8; *id.* at 27–29, 133:22–135:5; *id.* at 32–33, 140:18–141:23.) Dr. Baughman, the surgeon who performed this surgery on Plaintiff, offered the following analogy to explain the procedure:

> [The] intestine is sort of like a garden hose, and if you imagine that you cut like a foot section out of the garden hose and you needed to put the two ends back together, putting the two ends back together would be creating an anastomosis, so it's restoring continuity to the structure. . . . [I]t's putting the two parts back together and creating a connection such that you restore continuity.

(*Id.* at 5–6, 31:17–32:4.) Following such surgeries, as Dr. Baughman clarified, the anastomoses created will leak in roughly 20% percent of patients (i.e., about "1 in 5") for various reasons. (*Id.* at 9, 43:11–21; *id.* at 50–51, 177:19–178:15.)

C. Plaintiff's Surgery

On October 16, 2019, Dr. Baughman performed the sigmoidectomy at Grand Strand Regional Medical Center in Myrtle Beach, South Carolina. (DE 41 at 9 ¶ 29.) The surgery followed standard procedure: an excision of Plaintiff's sigmoid colon followed by the reattachment of Plaintiff's descending colon to the portion of the colon near his rectum. (DE 75-3 at 17–18, Baughman Dep. 117:24–118:15; *id.* at 21–22, 124:24–125:7; *id.* at 22–23, 128:3–129:4; *id.* at 27–29, 133:22–135:5; *id.* at 38–39, 146:17–147:6.)

To complete the first step—i.e., excision of the sigmoid colon—Dr. Baughman utilized both a linear stapler and a curved "contour" stapler.[3] (*Id.* at 18, 118:4–15 (discussing the use of linear stapler to divide the sigmoid colon from the descending colon); *id.* at 20, 123:1–124:8 (discussing the use of a contour stapler to divide the sigmoid colon from the rectum)).

To complete the second step—i.e., reconnection of Plaintiff's colon—Dr. Baughman used a circular stapler made by EES ("Stapler"). (*Id.* at 30, 136:15–20.) In this procedure, Dr. Baughman sewed an "anvil" into the proximal end of Plaintiff's colon where the portion of the colon had been removed. (*Id.* at 24–26, 129:19–131:17.) Dr. Baughman then passed the Stapler through Plaintiff's rectum to the distal end of Plaintiff's colon, where the portion of the colon had been removed. (DE 75-3 at 28–29, Baughman Dep.134:13–135:5.) The anvil and Stapler were then joined, bringing the two portions of the colon together. (*Id.* at 28–29, 134:18–135:5.) The Stapler was then fired, creating an anastomosis that connected the two ends of the colon. (*Id.* at 6–7, 32:22–33:9; *id.* at 27–29, 133:15–135:5; *id.* at 31–39, 139:12–147:6; *id.* at 40, 152:6–16.) Dr. Baughman had no indication of any malfunction with the Stapler nor any concern about the success of the surgery. (*Id.* at 43–44, 161:8–162:12.)

After Dr. Baughman completed the anastomosis, he performed two "leak tests" to ensure the Stapler had properly functioned. (*Id.* at 42, 160:3–6.) To perform a "leak test,"

> the pelvis is filled up with . . . saline . . . to make sure that [the surgeon] can appreciate if there are any bubbles. And then [the surgeon] instill[s]

[3] Neither the linear stapler nor the contour stapler made the staple line at the anastomosis site, and therefore, are not at issue in this case.

> air into the rectum. . . . [The surgeon] blow[s] up the rectum with air, and then [he] sort of manipulate[s] it to see if there are bubbles coming from anywhere along the staple line.

(*Id.* at 41, 159:12–21.) The two leak tests revealed no escaping air or bubbles. (DE 75-3 at 42, Baughman Dep. 160:20–24.) Dr. Baughman was satisfied with the surgery and had no indication of any problem with any of the staples the Stapler deployed. (*Id.* at 43–44, 161:24–162:8.) Dr. Baughman testified to the following:

> Q. And, Doctor, looking back on this, if you were in the position today with the knowledge that you had that you've got today and you were seeing Mr. Eichin before the surgery, would you still change anything about what you did initially? And that is using a surgical stapler to form the anastomosis line?
>
> A. I mean, I think based off of what I can recall from the documentations that's been provided, I don't see a reason that I would have felt the need to change anything, no.

(*Id.* at 69, 199:14–24.)

D. Plaintiff's Revision Surgery

Plaintiff remained in the hospital for several days following his sigmoidectomy. (*See id.* at 45–46, 167:18–168:8.) During this time, Plaintiff's heart rate was abnormally high. (*Id.* at 45–46, 167:18–168:11; *id.* at 47, 172:2–13.) On October 21, 2019, a CT scan revealed a significant amount of free air in Plaintiff's abdomen. (DE 75-3 at 48-49, Baughman Dep. 175:18–176:4.)

Later that day, Plaintiff underwent a revision surgery performed by Dr. Baughman and Dr. Brant Clatterbuck ("Dr. Clatterbuck"). (*Id.* at 51, 178:16–20; *id.* at 52–53, 179:23-180:19.) They identified a small hole at the anastomosis site of less than one centimeter and sewed the hole closed. (*Id.* at 54–55, 182:6–183:22; *id.* at 59, 188:4–17.) Although the operative note states that the "leak appeared to be due to a

small area of nonfunctional staples" (*id.* at 56, 185:7–11), Dr. Baughman did not attribute this hole or the "nonfunctional staples" to any issue with the Stapler itself or even the surgery. (*Id.* at 57–58, 186:16–187:20.)

Instead, Dr. Baughman understood Plaintiff to be at a heightened risk for a staple line leak due to possible complications caused by the "quality of tissue that is being joined together" which could be affected by "other conditions that a patient has" including "chronic[] inflam[mation]" and did not necessarily attribute the small leak in Plaintiff's colon to the Stapler. (DE 75-3 at 60–62, Baughman Dep. 190:6–192:15.)

Following his revision surgery, Plaintiff completed post-operative treatment and follow-up appointments with Dr. Baughman. (*Id.* at 62–67, 192:16–197:22.)

E. This Lawsuit

Plaintiff claims that, following the removal of a portion of his colon during surgery, the circular surgical stapler used to reconnect the two ends of his colon failed to fire, which subsequently led to a leak at the site where the two ends of his colon were reconnected. (*See* DE 41 at 9 ¶¶ 29–31.) Plaintiff originally sued multiple other parties (*see* DEs 1, 19) but now pursues claims only against EES—the makers of the stapler at issue.[4] (*See* DEs 52, 70.)

EES argues that it is entitled to summary judgment on each of Plaintiff's claims because, among other reasons,

(1) Plaintiff failed to identify or submit the written report of any expert by his March 15, 2024, deadline under the Court's Fifth Consent Amended Scheduling Order (DE 75 at 2 ¶ 3);

[4] Defendant Ethicon Endo-Surgery LLC is the legal manufacturer of certain staplers. (DE 66 at 2 ¶ 4). Defendant Ethicon Endo-Surgery, Inc., is involved in the design and marketing of certain surgical stapler devices. (DE 65 at 3 ¶ 8.)

(2) Plaintiff's "Strict Products Liability – Failure to Warn" must fail because Plaintiff's surgeon testified that he would have used the surgical stapler at issue even if he knew before Plaintiff's surgery everything he knows now about the stapler (*id.* at 3 ¶ 4); and

(3) there is no evidentiary or legal support for Plaintiff's negligence claims. (*Id.* at 3–4 ¶ 6.)

LEGAL STANDARD

"[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "Under Rule 56(c), summary judgment is proper 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Id.* at 322. "A fact is 'material' if proof of its existence or non-existence would affect disposition of the case under applicable law. An issue of material fact is 'genuine' if the evidence offered is such that a reasonable jury might return a verdict for the non-movant." *Wai Man Tom v. Hosp. Ventures LLC*, 980 F.3d 1027, 1037 (4th Cir. 2020) (citation omitted). If the burden of proof at trial would be on the nonmoving party "a summary judgment motion may properly be made in reliance solely on the 'pleadings, depositions, answers to interrogatories, and admissions on file.'" *Celotex Corp.*, 477 U.S. at 324. "[T]he burden on the moving party may be discharged by 'showing'— that is, pointing out to

the district court—that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. "If the moving party has not fully discharged this initial burden of production, its motion for summary judgment must be denied . . . ." *Id.* at 332 (Brennan, J., dissenting).

Accordingly, once the movant has made this threshold demonstration, to survive the motion for summary judgment, pursuant to Rule 56(e), the nonmoving party must "go beyond the pleadings and by h[is] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex Corp.*, 477 U.S. at 324 (citation omitted). Under this standard, "the mere existence of a scintilla of evidence" in favor of the non-movant's position is insufficient to withstand the summary judgment motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). "Likewise, conclusory allegations or denials, without more, are insufficient to preclude granting the summary judgment motion." *Wai Man Tom*, 980 F.3d at 1037.

"Summary judgment cannot be granted merely because the court believes that the movant will prevail if the action is tried on the merits." *Jacobs v. N.C. Admin. Office of the Cts*, 780 F.3d 562, 568 (4th Cir. 2015) (quoting 10A Charles Alan Wright et al., *Federal Practice & Procedure* § 2728 (3d ed. 1998)). "The court may grant summary judgment only if it concludes that the evidence could not permit a reasonable jury to return a favorable verdict." *Sedar v. Reston Town Ctr. Prop., LLC*, 988 F.3d 756, 761 (4th Cir. 2021). "Therefore, courts must view the evidence in the light most favorable to the nonmoving party and refrain from weighing the evidence

or making credibility determinations." *Variety Stores, Inc. v. Wal-Mart Stores, Inc.*, 888 F.3d 651, 659 (4th Cir. 2018) (internal quotation marks omitted and alterations adopted). A court improperly weighs the evidence if it fails to credit evidence that contradicts its factual conclusions or fails to draw reasonable inferences in the light most favorable to the nonmoving party. *See id.* at 659–60.

DISCUSSION

A. Motion to Amend Scheduling Order

Since a resolution of Plaintiff's motion to amend the Fifth Amended Scheduling order resolves several issues raised in EES's summary judgment motion, the Court will address Plaintiff's motion to amend first.

1. The Parties' Arguments

In support of his motion to amend, Plaintiff contends, among other things, that

> Plaintiff has not been able to retain an expert due to Defendants' failure to answer Plaintiff's discovery with complete answers. Rather, Defendants answered Plaintiff's discovery requests with boilerplate answers and failed to provide any information regarding the stapler(s) Plaintiff requested information. Plaintiff has consulted with Defendants regarding this discovery issue pursuant to Rule 11, FRCP and the Local Civil Rules, and a forthcoming Motion to Compel regarding the same is forthcoming.

(DE 77.) Plaintiff also argues that under Rule 37(c), Fed. R. Civ. P., summary judgment should be denied because Plaintiff's failure to meet the expert disclosure deadline is substantially justified and harmless. (DE 82 at 3) (citing *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592 (4th Cir. 2003)). EES opposes the motion, stating,

> Plaintiff's Motion should be denied because (1) Plaintiff has not demonstrated "excusable neglect" under Rule 6 for his failure to disclose

> an expert by his March 15, 2024 deadline; (2) Plaintiff has not demonstrated "extraordinary circumstances" for his untimely motion filed three weeks after the expert deadline and one week after Defendants' summary judgment motion; and (3) any extension of Plaintiff's expert deadline would be futile.

(DE 79 at 5.)

2. The Applicable Standard for Plaintiff's Motion to Amend

The Court first considers the applicable rule that controls this matter. Although Rule 37(c)'s "substantially justified" or "harmless" standards are two exceptions to the general rule excluding evidence that a party seeks to offer at trial or a hearing but has failed to properly disclose, Plaintiff has *not* attempted to offer an expert or his report in opposition to EES's claims. And so, Rule 37(c), Fed. R. Civ. P., does not apply.

Where, as here, a party seeks leave to retain and file his expert disclosures *after* the deadline established by the scheduling order has passed, two Federal Rules of Civil Procedure are implicated: Rules 6(b)(1)(B) and 16(b)(4). First, Rule 6(b)(1)(B), Fed. R. Civ. P., provides that "[w]hen an act may or must be done within a specified time, the court may, for good cause, extend the time . . . on motion made after the time has expired if the party failed to act because of excusable neglect." Other courts in this Circuit have held that "[t]he good cause modification provision specific to Rule 16(b)(4) takes precedence over the generally applicable extension provisions of Rule 6(b)(1)." *United States ex rel. Manganaro Midatlantic LLC*, No. PX-16-2816, 2018 U.S. Dist. LEXIS 135059, at *2 (D. Md. Aug. 10, 2018) (collecting cases).

Rule 16(b)(4) allows a scheduling order to be modified "only for good cause and with the judge's consent." Rule 16(b)(4), Fed. R. Civ. P. "Good cause" under Rule

16(b)(4) does not focus on the prejudice to the non-movant or bad faith of the moving party, but rather on the moving party's diligence. *See Dilmar Oil Co., Inc. v. Federated Mut. Ins. Co.*, 986 F. Supp. 959, 980 (D.S.C. 1997), *aff'd by unpublished opinion*, 129 F.3d 116, 1997 WL 702267 (4th Cir. 1997)); *see also Cook v. Howard*, 484 F. App'x 805, 815 (4th Cir. 2012) (per curiam) ("'Good cause' requires 'the party seeking relief [to] show that the deadlines cannot reasonably be met despite the party's diligence,' and whatever other factors are also considered, 'the good-cause standard will not be satisfied if the [district] court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule.'") (quoting 6A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1522.2 (3d ed. 2010)); *McDonald v. Marlboro County*, No. 5:12-CV-1725-RBH-KDW, 2013 WL 6580631, at *4 (D.S.C. Dec. 16, 2013) ("[T]he key to the 'good cause' analysis of Rule 16 is whether the party was diligent in seeking to amend."); Fed. R. Civ. P. 16(b), advisory committee's note (1983 amendment) ("[T]he court may modify the schedule on a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension.").

The party moving to modify a scheduling order bears the burden of demonstrating the existence of good cause. *United States v. Cochran*, No. 4:12-CV-220-FL, 2014 WL 347426, at *2 (E.D.N.C. Jan. 30, 2014) (citing *Nourison Rug Corp. v. Parvizian*, 535 F.3d 295, 298 (4th Cir. 2008)). "A scheduling order is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without

peril." *Jordan v. E.I. du Pont de Nemours & Co.*, 867 F. Supp. 1238, 1250 (D.S.C. 1994).

3. Plaintiff Has Failed to Show Good Cause

The timeline here does not show that the schedule could not be met despite the diligence of Plaintiff. Plaintiff's alleged injury occurred on October 16, 2019. (DE 1 at 6 ¶ 21). On October 6, 2021, Plaintiff filed his Complaint.[5] (*Id.*) On March 14, 2022, discovery began. (*See* DE 23 at 2). On December 14, 2022, EES answered Plaintiff's amended complaint. (DEs 48, 49; *see* DEs 65, 66 (answering following amendment to pleadings to name only EES entities).)

On May 22, 2023, the Court extended the expert disclosure deadline to December 15, 2023, (*see* DE 56 at 1 ¶ 2), and on November 30, 2023, the Court again extended it to March 15, 2024. (DE 69 at 1 ¶ 2.) On January 11, 2024, the parties deposed the treating surgeon, Dr. Baughman. (DEs 75-3, 82-4.) Notably, the Fifth Amended Scheduling Order—the operative scheduling order in this case—required Plaintiff to "identify all evidence relat[ed] to product identification of the [surgical] stapler" used during Plaintiff's surgery no later than February 15, 2024. (DE 69 at 1 ¶ 1.)

On February 16, 2024, Plaintiff served discovery requests on EES (DE 82 at 6), and EES responded to those discovery requests on March 18, 2024. (*See* DE 82-2 at 34.) However, as noted, *Plaintiff's* expert disclosures were due on March 15, 2024. (DE 69 at 1 ¶ 2.) Nevertheless, about two-and-a-half weeks after the deadline, on

[5] Plaintiff amended his complaint by right on February 25, 2022. (DE 41.)

April 4, 2024, Plaintiff moved to extend his deadline to file his expert disclosure. (*See* DE 77.)

Plaintiff says he has been unable to retain an expert because EES failed to provide him "with complete answers" to his discovery, "and a forthcoming Motion to Compel regarding the same is forthcoming." (DE 77 at 1 ¶ 3.) Plaintiff also says, "despite Plaintiff's diligent efforts, the model number of the surgical staples at issue (ECS33A model) was not ascertained until December 2023." (*Id.* at 1 ¶ 4.)

Plaintiff's arguments do not demonstrate diligence. Instead, they simply frame the fact that Plaintiff waited almost four months from his December receipt of the identity of the Stapler to pursue this amendment, and Plaintiff did so nineteen days *after* the materials he seeks to obtain were due. Even now, no motions to compel are pending before the Court,[6] and the deadline to challenge the sufficiency of EES's discovery responses too has passed. *See* Local Civ. Rule 37.01 (D.S.C.) ("Motions to compel discovery must be filed within twenty-one (21) days after receipt of the discovery response to which the motion to compel is directed or, where no response has been received, within twenty-one (21) days after the response was due.").

Plaintiff has offered no evidence showing his diligence in seeking leave to amend the Scheduling Order or any impediments to the same. Instead, without justification, Plaintiff has failed to comply with the Fifth Amended Scheduling Order

[6] The Court also notes that the Fifth Amended Scheduling order provides that "No motions relating to discovery shall be filed until counsel . . . have had a telephone conference with Judge Dawson in an attempt to resolve the matter informally. The request for a telephone conference should be made within the time limit prescribed by local rule for filing such motion." (DE 69 at 2 ¶5.) No such request has been received by the Court.

by "fil[ing] and serv[ing] a document identifying . . . each person whom Plaintiff expects to call as an expert at trial . . . by March 15, 202[4]." (DE 69). To date, Plaintiff has still not informed the Court of a retained expert or sought leave to file a written report by an expert. Accordingly, Plaintiff's motion to amend is denied.

B. Summary Judgment

1. Plaintiff's Product Liability Claims

Plaintiff's Second Amended Complaint (DE 41) asserts three claims: (1) "Strict Products Liability Manufacturing Defect"; (2) "Negligence"; and (3) "Strict Products Liability – Failure to Warn[.]" (*Id.* at 13–17 ¶¶ 43–63.)

EES argues that it is entitled to summary judgment on each of Plaintiff's claims because, among other reasons, (1) Plaintiff failed to identify or submit the written report of an expert; (2) Plaintiff's "Strict Products Liability – Failure to Warn" claim must fail because Plaintiff's surgeon testified that he would have used the surgical stapler at issue even if he knew before Plaintiff's surgery everything he knows now about the stapler; and (3) there is no evidentiary or legal support for Plaintiff's Negligence claims. (DE 75.)

Since the Court agrees with EES's first reason, the Court declines to reach its alternative grounds.

2. Plaintiff's Failure to Proffer Expert Testimony Is Fatal to His Claims

"[T]here are three defects a plaintiff in a products liability lawsuit can allege: 1) a manufacturing defect, 2) a warning defect, and 3) a design defect." *Watson v. Ford Motor Co.*, 389 S.C. 434, 444, 699 S.E.2d 169, 174 (2010). A product liability

action "may be brought under several theories, including negligence, strict liability, and warranty." *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 538, 462 S.E.2d 321, 325 (S.C. Ct. App. 1995).

"[I]n order to find liability under *any* products liability theory, the plaintiff must show: (1) he was injured by the product; (2) the injury occurred because the product was in a defective condition, unreasonably dangerous to the user; and (3) that the product at the time of the accident was in essentially the same condition as when it left the hands of the defendant." *Bragg*, 319 S.C. at 539, 462 S.E.2d at 326 (emphasis added); *see Dema v. Shore Enters., Ltd.*, 312 S.C. 528, 530, 435 S.E.2d 875, 876 (S.C. Ct. App. 1993).

"The general rule in South Carolina is that[,] where a subject is beyond the common knowledge of the jury, expert testimony is required." *Babb v. Lee Cty. Landfill SC, LLC*, 405 S.C. 129, 153, 747 S.E.2d 468, 481 (2013). Further, as the South Carolina Supreme court has written,

> Deciding what is within the knowledge of a lay jury and what requires expert testimony depends on the particular facts of the case, including the complexity and technical nature of the evidence to be presented and the trial judge's understanding of a lay person's knowledge. . . . Ultimately, due to the fact-specific nature of the determination, it is a question that must be left within the discretion of the trial judge.

Id.

a. *Plaintiff's Failure to Demonstrate the Existence of a Defect*

To establish defectiveness in a technically complex case, a plaintiff must come forward with relevant and reliable expert testimony. *See Graves v. CAS Med.Sys., Inc.,* 401 S.C. 63, 79, 735 S.E.2d 650, 659 (2012) (discussing the need for expert

testimony in complex cases); *see Sunvillas Homeowners Ass'n, Inc. v. Square D Co.*, 301 S.C. 330, 391 S.E.2d 868, 871 (S.C. Ct. App.1990) (noting "[i]n [negligence, warranty, and strict liability cases] the plaintiff must establish the product was in a defective condition")

Here, in Plaintiff's negligence claim, Plaintiff contends that he

> was harmed by Defendants' defective surgical staplers, which were distributed, manufactured, and sold by Defendants. Defendants' surgical staplers contained a design defect that made the products unreasonably dangerous to patients. Specifically, there was a design or manufacturing defect that would result in a stapler failing to fire staples, despite proper utilization by a surgeon. That design defect in the staplers existed when those products left the manufacturer's control.

(DE 41 at 15 ¶ 55.)

Expert testimony is necessary to establish this claim. *See Disher v. Synthes (U.S.A.)*, 371 F. Supp. 2d 764, 773 (D.S.C. 2005) (granting summary judgment in humeral nail case after disregarding plaintiff's expert testimony and noting "[s]ince plaintiff has failed to proffer expert testimony sufficient to permit a jury to conclude that the Nail was defective and unreasonably dangerous, defendant is entitled to summary judgment on plaintiff's sole [design defect] strict liability claim"); *Nobles v. DePuy Synthes Sales, Inc.*, 471 F. Supp. 3d 717, 724 (D.S.C. 2020) (granting summary judgment in mandibular reconstruction plate case after excluding plaintiff's expert, because "[t]he issues of the proper design of the product in question . . . [we]re matters outside the lay expertise of jurors" and "Plaintiffs lack[ed] an expert witness to render a legally acceptable opinion under Rule 702 regarding any alleged defect in the design of the product").

The "complexity and technical nature" of a surgical stapler dictates that expert evidence must be presented. *Cf. Nobles*, 471 F. Supp. 3d at 722. Moreover, Plaintiff must articulate what the purported defect is and a feasible alternative design. *Branham v. Ford Motor Co.*, 390 S.C. 203, 218–25, 701 S.E.2d 5, 13–17 (2010). Thus, "[w]ithout expert testimony to fill this evidentiary gap, [P]laintiff cannot, as a matter of law, establish that the [Stapler] was defective or unreasonably dangerous."[7] *See Disher*, 371 F. Supp. 2d at 770.

b. *Plaintiff's Failure to Demonstrate Causation*

Plaintiff's product liability claims also fail for lack of expert testimony on causation. A manufacturing defect claim in South Carolina is an allegation "that a particular product was defectively manufactured." *Watson*, 389 S.C. at 444, 699 S.E.2d at 174. To recover on his manufacturing and design defect claims, Plaintiff must establish that the "product defect was the proximate cause of the injury

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[7] Equally, Plaintiff cannot establish his "Strict Products Liability – Failure to Warn" claim, without expert testimony. Plaintiff contends, among other things that,

> Defendants knew that their surgical staplers posed a risk to patients when used as intended because certain units were manufactured without a component that resulted in a failure to form a staple line that caused stapler cutting tissue, by the staples failing to "fire". Despite knowing about this defect, Defendants failed to adequately warn potential surgeons or patients at the time they discovered, or should have discovered, those defects. Defendants manipulated the warning systems in a way that ensured healthcare providers could not review the dangers posed by the products.

(DE 41 at 17 ¶ 62.) The inadequate warning issue here—i.e., whether the EES Defendants' warnings adequately educated physicians of the risk of failed fires with or leakage following use of the Stapler—lies beyond the ken of jurors. Indeed, it turns on the knowledge, training, and experience of physicians, and it is precisely the type of information that is the subject of expert testimony. *See* Rule 702, Fed. R. Evid. ("A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue . . . .").

sustained."[8] *Small v. Pioneer Mach., Inc.*, 329 S.C. 448, 463, 494 S.E.2d 835, 842 (S.C. Ct. App. 1997). "Proximate cause requires proof of both causation in fact and legal cause." *Id.* "Causation in fact is proved by establishing the injury would not have occurred but for the defendant's negligence [while l]egal cause is proved by establishing foreseeability. *Id.* "The touchstone of proximate cause in South Carolina is foreseeability." *Id.* "The test of foreseeability is whether some injury to another is the natural and probable consequence of the complained-of act." *Id.* Courts in this district "have defined a manufacturing defect as existing 'when a product does not conform to the design standards and blueprints of the manufacturer and the flaw makes the product more dangerous and therefore unfit for its intended or foreseeable uses.'" *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 818 (D.S.C. 2011) (quoting another source), *see also Stratton*, 2021 WL 5416705, at *3.

"Where a medical causal relation issue is not one within the common knowledge of the layman, proximate cause cannot be determined without expert medical testimony." *In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liability Litig.*, 693 F. Supp. 2d 515, 518 (D.S.C. 2010) (quoting *Goewey v. United States*, 886 F. Supp. 1268, 1279 (D.S.C. 1995)); *see also Disher*, 371 F. Supp. 2d at 769 (citing *Jones v. Danek Med., Inc.*, No. 4:96-3323-12, 1999 WL 1133272, at *4 (D.S.C. Oct. 12, 1999)). Here, Plaintiff alleges that the Stapler's purported malfunction proximately caused his injuries. (*See, e.g.*, DE 41 at 14 ¶ 51.) However, Plaintiff

[8] "Proximate causation is critical to any theory under which a products liability case proceeds . . . ." *Stratton v. Merck & Co.*, No. CV 2:21-02211-RMG, 2021 WL 5416705, at *4 (D.S.C. Nov. 17, 2021)

designated no expert to opine that the purported malfunction proximately caused his injuries.

Even so, regarding his "Strict Products Liability Manufacturing Defect" claim, Plaintiff argues that summary judgment is inappropriate for two reasons. First, "a products liability case alleging a manufacturing defect does not require the Plaintiff to present expert testimony." (DE 82 at 9.) Secondly, Plaintiff argues that his treating physicians (Dr. Baughman and Dr. Clatterbuck) cannot state to a reasonable degree of medical certainty whether the stapler was or was not the cause of the leak. (*Id.* at 9–10.) And so, Plaintiff believes, "based on Dr. Baughman's and Dr. Clatterbuck's statements, there are questions of material fact as to whether the ECS33A circular stapler used during Plaintiff's surgery was defective and caused the anastomotic leak." (*Id.*)

The Court rejects both contentions. First, although an expert may not be needed to determine whether a product was defectively manufactured in *all* cases, as Plaintiff concedes by his belated request to retain an expert, the "complexity and technical nature" of a surgical stapler dictates that expert evidence must be presented. *Cf. Nobles*, 471 F. Supp. 3d at 722. Secondly, as for Dr. Baughman's and Dr. Clatterbuck's testimony, Plaintiff has misused and misapplied the import of the same. To meet his burden of proof, Plaintiff must offer a medical expert that can testify *affirmatively* and to a reasonable degree of medical certainty that a defect in the Stapler caused his injury. *See Riggins v. SSC Yanceyville Operating Co., LLC*, 800 F. App'x 151, 157 (4th Cir. 2020) (applying North Carolina law). Here, Plaintiff

failed to identify either Dr. Baughman or Dr. Clatterbuck as experts—rendering reference to their testimony improper. Nevertheless, even if Plaintiff had named either as an expert for medical causation, Plaintiff acknowledges the dispositive shortcoming in their testimony: they cannot say to a reasonable degree of medical certainty *what* caused Plaintiff's purported injuries.

As *the plaintiff* in this case, Plaintiff has the "burden of proof in establishing h[is] injuries were proximately caused by" some actionable conduct of EES. *Harris v. Rose's Stores, Inc.*, 315 S.C. 344, 347, 433 S.E.2d 905, 907 (S.C. Ct. App. 1993). The only meaningful evidence on this point is the testimony of Dr. Baughman and Dr. Clatterbuck. Both surgeons testified that leaks are a known risk that can occur even without a product defect or other wrongdoing. (*See e.g.*, DE 82-4 at 2, Baughman Dep. 186:16–188:3; DE 82-5 at 2, Clatterbuck Dep. 47:18–48:16.) And both refused to testify to a reasonable degree of medical certainty that a defect in the surgical stapler at issue caused Plaintiff's injury. (*See* DE 75-3 at 62, Baughman Dep. 192:9–15; DE 75-4 at 7, Clatterbuck Dep. 47:18–25.)

An expert's inability to decisively testify to the cause of injury does not satisfy the plaintiff's burden of proof. Quite the opposite: It entitles a defendant to summary judgment. *See Harris*, 315 S.C. at 347, 433 S.E.2d at 907. Because Plaintiff cannot establish the proximate cause of any alleged injury through an expert, EES is entitled to summary judgment on Plaintiff's product liability claims. *See Disher*, 371 F. Supp. 2d at 770 ("[P]laintiff must establish proximate cause through competent expert testimony.").

CONCLUSION

For these reasons, the Court denies Plaintiff's "Motion to Amend Scheduling Order" (DE 77) and grants Defendants' "Motion for Summary Judgment" (DE 75). Given these rulings, the Court dismisses this case.

IT IS SO ORDERED.

Joseph Dawson, III
United States District Judge

Florence, South Carolina
October 24, 2024